K012035

JUL 27 2001

510(k) Summary

Special 510(k) Summary of Safety and Effectiveness

Company information

Braun GmbH
Frankfurter Strasse 145
D-61476 Kronberg
Germany

Device Identification

Trade Name – Braun PrecisionSensor™ Pro (BP2590)
Classification Name – Wrist blood pressure monitor
Classification – Class II
Product Code – 74 DXN

Predicate Device

Braun PrecisionSensor™ (BP2000 Series) wrist blood pressure monitor.

Device Description

The PrecisionSensor Pro is a non-invasive wrist blood pressure monitor that measures and displays systolic and diastolic blood pressure, and pulse rate. The values are ascertained by the oscillometric method.

Intended Use

The PrecisionSensor™ Pro (BP2590) is intended to be used for the noninvasive measurement of blood pressure (systolic and diastolic) and pulse rate in adults in a professional environment.

Intended Patient Population

Adults are the intended patient population to use this device.

Intended Environment of Use

The intended environment of use is in professional medical environments (e.g., physician's offices, clinics, nursing homes, hospitals) where blood pressure may be measured.

Indications for Use

The Braun PrecisionSensor™ Pro (BP2590) wrist blood pressure monitor is indicated for use for the noninvasive measurement of blood pressure (systolic and diastolic) and pulse rate in adults, in a professional environment. Use may be initiated as part of a hypertension screening, monitoring, and/or management program supervised by a healthcare provider.

Comparison of the Braun PrecisionSensor™ Pro (BP2590) wrist blood pressure monitor to the Braun PrecisionSensor™ (BP2000 Series) wrist blood pressure monitor.

The basic design, intended use, and indications for use of the Braun PrecisionSensor Pro (BP2590) and the Braun PrecisionSensor™ (BP2000 Series) are similar. The fundamental scientific technology of the modified device has not changed from that of the predicate device.

The primary changes in the modified design of the Braun PrecisionSensor Pro (BP 2590) consist of reconfiguring the display and memory, and using a higher grade of Velcro for the cuff closure to make it robust for use in a professional environment while the predicate device, the Braun PrecisionSensor (BP2000 Series), is indicated for use in a home environment. To visually distinguish the professional use blood pressure monitor from the home use monitor, the color of the Velcro cuff was changed from blue to black and the monitor housing was changed from blue or white to silver.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2001

Braun GmbH
c/o Mr. Fred Schlador
Regulatory Resources, LLC
6183 Paseo Del Norte, Suite 150
Carlsbad, CA 92009

Re: K012035
Trade Name: Braun PrecisionSensor™ Pro, Model BP 2590
Regulatory Number: 21 CFR 870.1130
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: June 28, 2001
Received: June 29, 2001

Dear Mr. Schlador:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K012035

Device Name: PrecisionSensor™ pro (BP2590)
Wrist Blood Pressure Monitor

Indications for Use:

The Braun PrecisionSensor Pro (BP2590) wrist blood pressure monitor is indicated for use for the noninvasive measurement of blood pressure (systolic and diastolic) and pulse rate in adults, in a professional use environment. Use may be initiated as part of a hypertension screening, monitoring, and/or management program supervised by a healthcare provider.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use_____ OR Over the Counter ✓
(Per 21 CFR 801.109

03 002

Division of Cardiovascular & Respiratory Devices
510(k) Number K012035